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A randomized clinical trial investigating the effect of three vital tooth bleaching protocols on oral health-related quality of life

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ABSTRACT

Objectives: This study aimed to compare changes in oral health-related quality of life (OHRQoL) resulting from three vital tooth bleaching protocols.
Methods: The participants (n = 105) were randomly assigned to one of three vital bleaching treatment groups: home bleaching (HB), in-office bleaching (IOB), or combined bleaching (CB). HB involved the use of custom-made trays and 10% carbamide peroxide for a 14-day treatment period. IOB utilized 37.5% hydrogen peroxide applied in three cycles. CB treatment involved the use of IOB followed by HB. Tooth colour change was evaluated using a shade guide (ΔVS) and a digital spectrophotometry device (ΔES). The Oral Health Impact Profile-14 (OHIP-14) and Oral Impact on Daily Performance-22 (OIDP-22) instruments were used to assess changes in OHRQoL at baseline, 15-days and 6-month recalls. Linear mixed models were used to estimate between- and within-group differences.
Results: All bleaching protocols led to significant improvements in overall OHIP-14 scores at the 6-month recall ($p \leq 0.037$). CB and IOB treatments were associated with more substantial positive impacts on overall scores, psychological discomfort, physical disability (CB only), and psychological disability (CB only) compared to HB ($p \leq 0.011$). Significant enhancements in OIDP-22 scores were observed in the CB and HB groups at the 6-month recall compared to baseline ($p \leq 0.006$), with evidence indicating that these improvements were greater in the CB group compared to the IOB group ($p = 0.007$).
Conclusion: All bleaching treatments demonstrated a positive impact on OHRQoL. However, the positive impact was most consistent across domains and age groups in the CB group. The positive impact was less pronounced in older age groups.

1. Introduction

The value of physical beauty is undeniably emphasized in modern societies (Gehrke 1994). Physical attractiveness is commonly associated with positive personality traits (Montero, Gomez-Polo et al. 2014). Attractive individuals may be perceived as intelligent and accomplished, enjoying better life opportunities and experiences (Van der Geld, Oosterveld et al. 2007, Godinho, Goncalves et al. 2020). In the past decade, dental practitioners and patients have increasingly emphasized beauty and aesthetic restorations. Therefore, it is imperative for dental practitioners to provide restorations that match the patient's natural tooth colour (Jouhar, Ahmed et al. 2022). Tooth colour is a crucial element of an aesthetically pleasing smile, especially when it involves anterior teeth (Tin-Oo, Saddki et al. 2011, Montero, Gomez-Polo et al. 2014). Tooth discoloration is a common concern among males and females, across various age groups, different populations, and ethnicities, making it a major motivating factor for seeking aesthetic dental treatments (Qualtrough and Burke 1994). Consequently, vital tooth bleaching is one of the most requested cosmetic dental treatments (Morgan, Jum'ah et al. 2015, Loch, Ratnayake et al. 2019). Compared to

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restorative treatment modalities, vital tooth bleaching is considered minimally invasive since it requires no removal of tooth tissue. Therefore, potential adverse effects include transient sensitivity or gingival irritation, in contrast to the wide range of technical and biological complications associated with other restorative procedures (Morgan, Jum'ah et al. 2015, Rinke, Bettenhauser-Hartung et al. 2020). Vital tooth bleaching can be achieved using either carbamide peroxide (CP) or hydrogen peroxide (HP) (Haywood 1997). These bleaching agents can be applied directly to teeth by dental professionals under controlled conditions during in-office bleaching (IOB), or patients can apply the bleaching agent using a custom-made tray, commonly known as home bleaching (HB), or other self-prescribed over-the-counter products (Haywood 1997, Barghi 1998, Demarco, Meireles et al. 2009). Combining home and in-office bleaching has been recommended for achieving rapid tooth whitening while minimizing the application time of high-concentration hydrogen peroxide, potentially reducing side effects associated with this procedure (Deliperi, Bardwell et al. 2004, Kothari, Gray et al. 2019).

Social and psychological well-being are integral to overall health within the socio-environmental healthcare model. Subsequently, there have been recent investigations into the impact of disease or interventions on an individual's quality of life (QoL). Tooth discoloration has been significantly associated with general dental appearance dissatisfaction, particularly among females (Tin-Oo, Saddki et al. 2011). Moreover, dissatisfaction with one's smile has been correlated with social anxiety and self-consciousness among young adults (Daneshvar, Devji et al. 2015). A cross-sectional study revealed that even minor imperfections in dental aesthetics can significantly affect the perceived oral health-related quality of life (OHRQoL) (Klages, Bruckner et al. 2004). Another study demonstrated that using computer-aided image manipulation to enhance the brightness of teeth was significantly correlated with higher scores on the social appeal scale compared to darker or naturally coloured teeth. (Montero, Gomez-Polo et al. 2014). Furthermore, tooth bleaching has significantly improved important domains of young adults' OHRQoL, including satisfaction with facial aesthetics and reduced social anxiety (Bruhn, Darby et al. 2012).

A recent systematic review conducted by Kothari et al. revealed that four randomised controlled trials (RCTs) met the inclusion criteria for investigating the impact of vital tooth bleaching on OHRQoL. (McGrath, Wong et al. 2005, Bruhn, Darby et al. 2012, Meireles, Goettems et al. 2014, Martin, Vildosola et al. 2015, Kothari, Gray et al. 2019). The *meta*-analysis identified a consistent improvement trend in aesthetics-related domains, such as smiling and psychological discomfort. Additionally, there was notable heterogeneity among the studied populations, and most studies had relatively small sample sizes (Kothari, Gray et al. 2019). Furthermore, a recent randomised, placebo-controlled clinical trial with a large sample size demonstrated a significant improvement in overall OHRQoL among adults when assessed using the Oral Health Related-Quality of Life (OHIP-14) instrument, following home or in-office bleaching procedures (Goettems, Fernandez et al. 2021).

Few studies have examined the effectiveness of combined home and in-office bleaching protocol and its influence on patient satisfaction. To our knowledge, studies have yet to address the impact of this combined bleaching protocol on various aspects of OHRQoL. This study is the second part of a three-arm RCT, which has previously reported significantly superior short- and medium-term colour improvement with the combined bleaching protocol compared to home and in-office protocols (Kothari, Jum'ah et al. 2020). Additionally, we observed an improved self-perception of oral health and increased satisfaction with the smile and teeth whiteness in all groups (Kothari, Jum'ah et al. 2020). Our data also indicated that only young participants who received in-office or combined bleaching exhibited greater satisfaction with the straightness of their teeth (Kothari, Jum'ah et al. 2020). This paper presents our findings regarding the impact of combined, home, and in-office bleaching protocols on OHRQoL at the 15-day and 6-month recall. The null hypotheses tested in this study were as follows: (i) none of the bleaching protocols would have varying impacts on OHRQoL, as measured by OHIP-14 and OIDP-22 instruments, and (ii) there would be no correlation between shade changes and OHRQoL parameters.

2. Materials and methods

2.1. Study design, participants, and intervention

This study is the second part of a previously published three-arm, randomised, single-blind (with outcome assessors and a statistician-blinded) clinical trial. Detailed materials and methods, randomisation, and blinding procedures can be found in our previously published study (Kothari, Jum'ah et al. 2020). Ethical approval was obtained from the University of Otago Human Ethics Committee (Application no. H18/019), and the study was conducted in full accordance with the World Medical Declaration of Helsinki at the Faculty of Dentistry, University of Otago, Dunedin, New Zealand. The trial was registered in the Australia New Zealand Clinical Trial Registry (ANZCTR) and assigned the trial ID ACTRN12516001198415. The inclusion and exclusion criteria are outlined below:

Inclusion criteria: Sound, unrestored teeth 13–33, cervical third of teeth 13 and 33 darker than A3.

Exclusion criteria: Active caries or periodontal disease, dentine hypersensitivity, undergoing orthodontic treatment, pregnancy or breastfeeding, smoking, known allergy to bleaching product(s).

A sample size of 31 participants per group was determined to detect differences between groups using OHIP-14 (Núñez, Dreyer et al. 2013, Bersezio, Estay et al. 2019) and OIDP-22 (Baker, Pankhurst et al. 2006) scores with 80% power using two-sided tests at the 0.05 level. A sample of 35 per study group was selected to compensate for a 10% potential withdrawal, loss to follow-up, or participant exclusion owing to adverse effects such as severe sensitivity. Participants (n = 35 per group) were randomly assigned to three groups based on the bleaching protocol as follows:

Home bleaching (HB): Participants used a custom-made tray to apply 10% carbamide peroxide (CP) bleaching gel (Polanight, SDI, Australia) for 8 h at night over a 14-day period.

In-office bleaching (IOB): High-concentration hydrogen peroxide (HP) (37.5%, Pola in-office+, SDI, Australia) was applied for 8 min on the labial/buccal surfaces of the teeth. This process was repeated 3 times; the bleaching agent was aspirated using high volume suction and rinsed with copious amounts of water between cycles.

Combination (CB): Participants underwent IOB followed by HB, following the same protocol described earlier.

Shade measurements were recorded using a value-oriented shade guide [ΔVC] (Vitapan Classical, VITA Zahnfabrik, Germany) and a digital spectrophotometry device [ΔES] (Vita Easyshade®, VITA Zahnfabrik, Germany), following the manufacturer's instructions (Vita Zahnfabrik, Bad Sackingen, Germany) (Kothari, Jum'ah et al. 2020).

2.2. OHRQoL analysis (OHIP-14 and OIDP-22)

The OHIP-14 instrument was administered to all participants before the intervention and again at the 15-day and 6-month recalls. The OHIP-14 questionnaire comprises seven dimensions (Table 1). Participants responded to the 14 questions related to these domains by selecting a single option on an ordinal scale (never = 0 points; rarely = 1 point; sometimes = 2 points; often = 3 points; and always = 4 points). A mean value was calculated for each domain. If a participant did not answer a question or if the question was not applicable, the response was recorded as the mean of the non-missing values for that patient in the corresponding domain. A higher average value across the seven dimensions indicated a more negative impact on an individual's OHRQoL. Table 1 lists the domains and questions found in the OHIP-14.

The oral impact on daily performance (OIDP) instrument was also administered before the intervention and at the 15-day and 6-month

Table 1
Domains and questions in the OHIP-14 and OIDP- 22 surveys.

OHIP-14 aesthetics survey	
Domain	**Questions**
Functional limitation	Have you noticed a tooth that does not look right? Have you felt that your appearance has been affected by problems with your teeth?
Physical pain	Have you had sensitive teeth for example to heat or cold food or drinks? Have you had painful areas in your mouth?
Psychological discomfort	Have you been self-conscious because of your teeth? Have you felt uncomfortable about the appearance of your teeth?
Physical disability	Have you felt that your food is less tasty because of problems with your teeth? Have you avoided smiling because of problems with your teeth?
Psychological disability	Have you found it difficult to relax because of problems with your teeth? Have you been a bit embarrassed because of problems with your teeth?
Social disability	Have you been less tolerant of your spouse or family because of problems with your teeth? Have you had difficulties doing your usual job because of problems with your teeth?
Handicap	Have you been unable to enjoy the company of other people very much because of problems with your teeth? Have you felt that life in general was less satisfying because of problems with your teeth?
OIDP-22 questions for one domain	
Questions	**Responses**
In the past (period), have you had any difficulty in (domain) due to problems with your mouth and teeth?	Yes = 1, proceed to question A No = 2, proceed to the question related to the next domain
Q(A): Have you had this difficulty on a regular basis over the past (period) or only part of this period?	On a regular basis = 1, proceed to question B For part of this period = 2, proceed to question C Have you had painful areas in your mouth?
Q(B): In the past (period), how often Have you had this difficulty owing to problems with your mouth and teeth? Skip Q(C)	Less often than once a month = 1 Approximately 1–2 times a month = 2 Approximately 1–2 times a week = 3 Approximately 3–4 times a week = 4 For 5 days or less = 1

recalls. This instrument assessed whether participants experienced any oral health-related problems in the preceding 4 weeks. The oral impact on daily performance was determined by summing scores for eight frequency items. These questions addressed difficulties related to oral health status, such as eating and enjoying food, speaking and pronouncing clearly, cleaning teeth, sleeping and relaxing, smiling and laughing without embarrassment, maintaining emotional well-being, enjoying social interactions, and fulfilling major work or social roles. The questions in the OIDP-22 survey are provided in Table 1.

2.3. Statistical analysis

The differences between the groups regarding changes in the outcomes (OHIP-14 and OIDP-22 scores) were examined using linear mixed models. Restricted maximum likelihood (REML) was used to estimate random effects for participants to accommodate the repeated measures. Interactions between time and group were employed to assess evidence for variations in changes between groups. Standard model diagnostics were used including inspecting histograms of model residuals, best linear unbiased predictions (BLUPs) of random effects, and scatter plots of residuals against fitted values and predictors. After evaluating models for each outcome using the complete dataset, we repeated the analyses for younger (<40 years) and older (≥40 years) participants. An age–time–group interaction term was incorporated to evaluate evidence for age-specific differences in changes between groups. These analyses were conducted using Stata (Version 15.1, Stata Corporation LLC, College Station, TX, USA), with two-sided $p < 0.05$ considered statistically significant.

3. Results

A total of 105 participants received one of the three investigated vital tooth bleaching protocols. The participants' ages ranged from 18 to 64 years, with a median (IQR) age of 28 (27) years. The majority of participants were females and younger than 40 years of age (62%). Table 2 presents the characteristics of the participants, and Fig. 1 provides a flowchart illustrating the clinical trial protocol.

3.1. OHIP-14 outcome

The mean (SD) baseline overall OHIP-14 scores of the participants in the HB, IOB, and CB groups were 14.3(8.3), 13.5(7.8) and 13.7(8.4), respectively. Significant differences in overall OHIP-14 scores were observed among all groups at the 6-month recall compared to baseline (all within-group $p \leq 0.037$), with more substantial improvements in the CB ($p = 0.001$) and IOB ($p = 0.011$) groups compared to HB. When evaluating within-group OHIP-14 score improvements in individual domains, all groups showed significant improvements in the functional limitation domain ($p \leq 0.018$), with no evidence of overall differences in changes (Wald $p = 0.113$). A pattern was observed across the other domains, where only CB and IOB exhibited within-group p-values below the significance level ($p \leq 0.041$). The CB and HB groups demonstrated significantly greater improvements in OHIP-14 scores compared to baseline in the following domains: psychological discomfort, physical disability (CB only), and psychological disability (CB only) compared to HB ($p \leq 0.011$).

Similar evidence for differences was found at the 15-day recall. The CB group exhibited significant improvement in the following parameters: overall OHIP-14 scores compared to the HB group ($p = 0.004$), functional limitations for CB and IOB compared to HB ($p \leq 0.025$), psychological discomfort for CB compared to HB ($p = 0.004$), and psychological disability for CB compared to IOB and HB ($p \leq 0.039$).

When considering participants younger than 40 years of age, significant differences in overall OHIP-14 scores were observed among all groups at the 6-month recall compared to baseline (all within-group p ≤

Table 2
Sample characteristic (values are counts and percentages unless otherwise specified).

Intervention		**CB**	**IOB**	**HB**	**Total**
No. of participants		35	35	35	105
Age	Median (IQR)	24(24)	28(28)	35(26)	28(27)
	Young (<40 yrs)	24(69)	22(63)	19(54)	65(62)
	Old (≥40 yrs)	11(31)	13(37)	16(46)	40(38)
Gender	Male	15(43)	13(37)	12(34)	40(38)
	Female	20(57)	22(63)	23(66)	65(62)
Ethnicity*	European	22(63)	22(63)	25(71)	69(66)
	Asian	8(23)	7(20)	5(14)	20(19)
	Māori	3(9)	4(11)	0(0)	7(7)
	Pacific	1(3)	1(3)	1(3)	3(3)
	Other	1(3)	1(3)	4(11)	6(6)
Education level	Secondary	7(20)	8(24)	12(38)	27(27)
	Post-secondary	13(37)	17(52)	6(19)	36(36.0)
	Tertiary	15(43)	8(24)	14(44)	37(37)
	Missing		2	3	

* Prioritised in the order of Māori, Pacific, Asian, Other, and European.

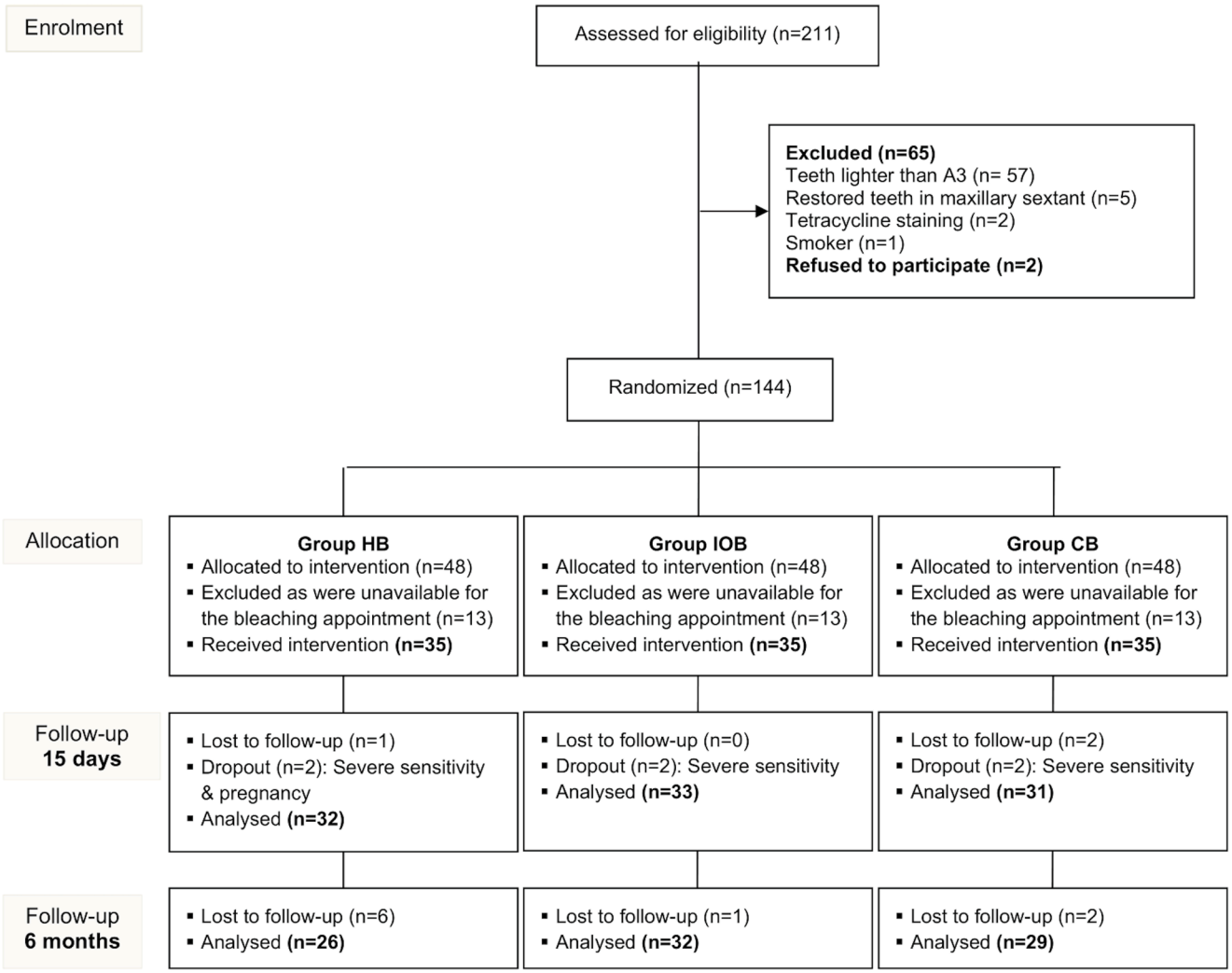

Fig. 1. Flowchart depicting various stages of the clinical trials and number of participants followed up following the three interventions.

0.017), with greater improvements in CB and IOB compared to HB ($p \leq 0.029$). In the older age group, a similar pattern of changes was observed, except for the HB group ($p = 0.474$), and there was no evidence that changes differed between treatments (Wald $p = 0.114$). Statistically significant age–group–time interactions were only observed in the physical pain and social disability domains ($p \leq 0.018$). Table 3 summarizes the OHIP-14 scores at baseline and recalls.

3.2. OIDP-22 outcome

The mean (SD) baseline OIDP-22 scores for all participants in the CB, IOB, and HB groups were 2.7(3.6), 1.6(2.6), and 2.9(7.0), respectively. Significant differences in overall OIDP-22 scores were observed between the CB and HB groups at the 6-month recall compared to baseline (within-group $p \leq 0.006$), with evidence that these changes were greater in CB compared to IOB alone ($p = 0.007$).

At the 15-day recall, there was no evidence of differences in changes between the groups (Wald $p = 0.686$).

No statistically significant age–group–time interactions were observed for changes (Wald $p = 0.129$). Considering participants younger than 40 years of age, there was no evidence that changes varied by group for younger or older participants at either 15 days or 6 months ($p \leq 0.185$), except for older participants at 6 months where CB was associated with greater improvements than both IOB and HB ($p \leq 0.012$). Table 3 summarizes the OIDP-22 scores at baseline and recalls.

3.3. Correlation between OHRQoL and shade improvement

Details of shade score improvements measured by the value-oriented shade guide (ΔVC) and digital spectrophotometry device (ΔES) are reported elsewhere [13] and summarized in Table 4.

Pairwise Pearson correlations were used to identify any associations between changes in OHIP-14, its subscales, or OIDP-22 scores, and ΔVS using all three groups combined. When using ΔVC, statistically significant positive correlations were observed between changes in overall OHIP-14 (coefficient = 0.23, $p = 0.025$) and psychological discomfort at the 15-day recall only (coefficient = 0.24, $p = 0.017$). When broken down by age group, the only significant correlation was observed between overall OHIP-14 score improvement and ΔVC (coefficient = 0.29, $p = 0.023$) at the 15-day recall in the younger age group. Table 5 shows these results for ΔVC (not ΔES, where there was no evidence of any associations, $p \leq 0.16$).

4. Discussion

Patient-centred clinical studies are invaluable for providing evidence regarding various treatments and are essential for determining the impact of such treatments on the OHRQoL of patients. OHRQoL measures are increasingly used to complement clinical indicators (Hongxing, List et al. 2014). In previously published work, a superior colour improvement was reported using the combined in-office and home

Table 3
OHIP-14 and OIDP-22 scores.

		Baseline			15 days			6 months		
QoL outcome	**Group**	**All**	**< 40 years**	**≥ 40 years**	**All**	**< 40 years**	**≥ 40 years**	**All**	**< 40 years**	**≥ 40 years**
OHIP overall	CB	14.3(8.3)	14.0(8.3)	14.9(8.6)	−6.2(7.0)^{a}	−7.7(6.9)^{a}	−1.8(5.5)^{a}	−8.1(5.7)^{a}	−8.9(5.8)^{a}	−6.5(5.5)^{a}
	IOB	13.5(7.8)	12.3(8.5)	15.7(6.0)	−3.7(6.1)^{ab}	−3.9(6.1)^{ab}	−3.5(6.3)^{a}	−7.0(6.1)^{a}	−7.6(6.3)^{a}	−6.0(6.0)^{a}
	HB	13.7(8.4)	13.5(8.5)	13.9(8.6)	−1.9(6.5)^{b}	−2.6(7.6)^{b}	−1.1(5.2)^{a}	−2.7(7.4)^{b}	−4.0(6.5)^{b}	−1.4(8.3)^{a}
Functional limitation	CB	2.9(2.0)	3.0(1.9)	2.5(2.2)	−0.8(1.9)^{a}	−1.3(1.8)^{a}	0.5(1.5)^{a}	−1.3(1.7)^{a}	−1.6(1.5)^{ab}	−0.9(2.0)^{a}
	IOB	2.7(1.9)	2.4(1.7)	3.4(2.1)	−0.8(1.7)^{a}	−0.8(1.5)^{a}	−0.8(2.1)^{a}	−1.4(1.7)^{a}	−1.6(1.7)^{a}	−1.2(1.7)^{a}
	HB	2.8(2.0)	2.6(2.0)	3.1(2.1)	0.2(2.2)^{b}	0.1(2.0)^{a}	0.4(2.4)^{a}	−0.7(1.4)^{a}	−0.5(1.6)^{b}	−0.8(1.1)^{a}
Physical pain	CB	1.9(1.5)	2.1(1.6)	1.5(1.0)	0.1(1.8)^{a}	−0.4(1.6)^{a}	1.4(2.1)^{a}	−0.5(1.5)^{a}	−0.6(1.6)^{a}	−0.2(1.2)^{a}
	IOB	2.5(1.2)	2.5(1.3)	2.4(1.1)	0.0(1.4)^{a}	−0.3(1.2)^{a}	0.5(1.5)^{ab}	−0.8(1.7)^{a}	−1.4(1.6)^{a}	0.0(1.6)^{a}
	HB	2.4(1.5)	1.9(1.5)	1.9(1.5)	0.0(1.1)^{a}	0.3(1.0)^{a}	−0.3(1.2)^{b}	−0.3(1.5)^{a}	−0.6(1.8)^{a}	0.0(1.2)^{a}
Psychological discomfort	CB	3.3(1.9)	3.5(1.9)	2.9(2.0)	−1.9(1.8)^{ab}	−2.3(1.7)^{a}	−0.8(1.5)^{a}	−2.0(1.5)^{a}	−2.3(1.2)^{a}	−1.4(1.9)^{a}
	IOB	3.0(2.0)	3.1(2.2)	2.9(1.7)	−0.9(1.8)^{b}	−1.1(1.9)^{a}	−0.8(1.6)^{a}	−1.6(1.6)^{a}	−1.9(1.6)^{a}	−1.1(1.6)^{ab}
	HB	3.4(1.9)	3.4(2.0)	3.4(2.0)	−0.7(1.9)^{b}	−1.0(2.1)^{a}	−0.3(1.8)^{a}	−0.5(1.9)^{b}	−1.1(2.0)^{a}	0.0(1.6)^{b}
Physical disability	CB	1.6(1.4)	1.3(1.4)	2.4(1.2)	−0.9(1.1)^{a}	−0.9(1.1)^{a}	−1.0(1.2)^{a}	−1.2(1.1)^{a}	−0.9(1.2)^{a}	−1.7(0.7)^{a}
	IOB	1.5(1.7)	1.5(1.9)	1.5(1.3)	−0.5(1.0)^{a}	−0.6(0.8)^{ab}	−0.4(1.3)^{a}	−0.7(1.4)^{ab}	−0.8(1.4)^{a}	−0.5(1.5)^{a}
	HB	1.4(1.3)	1.4(1.3)	1.5(1.3)	−0.4(1.1)^{a}	−0.4(1.3)^{b}	−0.4(0.9)^{a}	−0.2(1.3)^{b}	−0.4(1.1)^{a}	−0.1(1.6)^{b}
Psychological disability	CB	2.3(2.2)	2.2(2.0)	2.5(2.6)	−1.3(1.5)^{a}	−1.5(1.6)^{a}	−0.8(0.9)^{a}	−1.4(1.6)^{a}	−1.6(1.7)^{a}	−1.1(1.6)^{a}
	IOB	1.8(1.7)	1.6(1.8)	2.1(1.5)	−0.5(1.7)^{b}	−0.6(1.7)^{a}	−0.4(1.7)^{a}	−1.0(1.5)^{ab}	−1.0(1.7)^{ab}	−1.1(1.3)^{a}
	HB	1.9(1.7)	1.9(1.6)	1.9(1.8)	−0.5(1.3)^{b}	−0.9(1.4)^{a}	−0.1(1.0)^{a}	−0.5(1.7)^{b}	−0.6(1.6)^{b}	−0.4(1.9)^{a}
Social disability	CB	1.1(1.6)	0.8(1.6)	1.6(1.5)	−0.5(1.5)^{a}	−0.6(1.5)^{a}	−0.5(1.5)^{a}	−0.8(1.6)^{ab}	−0.9(1.7)^{a}	−0.6(1.1)^{a}
	IOB	0.8(1.2)	0.4(0.9)	1.5(1.3)	−0.4(1.0)^{a}	−0.2(0.5)^{a}	−0.7(1.4)^{a}	−0.6(1.1)^{b}	−0.3(0.8)^{b}	−1.0(1.3)^{a}
	HB	0.7(1.1)	0.5(0.9)	0.9(1.4)	−0.0(0.9)^{a}	−0.1(0.6)^{a}	0.0(1.2)^{a}	−0.1(1.3)^{a}	−0.2(0.7)^{b}	0.1(1.7)^{a}
Handicap	CB	1.2(1.5)	1.2(1.5)	1.5(1.4)	−0.7(1.3)^{a}	−0.7(1.5)^{a}	−0.6(0.9)^{a}	−0.9(1.4)^{a}	−1.0(1.3)^{a}	−0.6(1.5)^{a}
	IOB	1.2(1.3)	0.9(1.2)	1.8(1.3)	−0.6(1.3)^{a}	−0.3(1.3)^{a}	−1.0(1.3)^{a}	−0.8(1.1)^{a}	−0.6(0.9)^{a}	−1.2(1.3)^{a}
	HB	1.3(1.9)	1.3(1.9)	1.2(1.4)	−0.6(1.8)^{a}	−0.7(2.1)^{a}	−0.5(1.4)^{a}	−0.4(1.5)^{a}	−0.6(1.1)^{a}	−0.2(1.8)^{a}
OIDP overall	CB	2.7(3.6)	2.2(2.7)	3.8(5.1)	−0.6(3.5)^{a}	−0.1(2.8)^{a}	−2.1(4.9)^{a}	−2.1(3.3)^{a}	−1.7(2.4)^{a}	−2.8(4.5)^{a}
	IOB	1.6(2.6)	1.5(2.7)	1.8(2.6)	−0.1(1.5)^{a}	−0.4(1.7)^{a}	0.3(1.1)^{a}	−0.1(3.0)^{b}	−0.4(2.4)^{a}	0.5(3.7)^{a}
	HB	2.9(7.0)	3.9(9.1)	1.7(2.9)	−0.8(4.1)^{a}	−1.5(4.4)^{a}	−0.1(3.7)^{a}	−1.2(2.7)^{ab}	−1.6(3.1)^{a}	−0.8(2.3)^{b}

Baseline values represent the mean scores (SD).
Values at 15 days and 6 months represent the mean changes in OHIP-14 or OIDP-22 scores compared to baseline (SD).
Similar superscripted letters indicate a lack of statistical significance. Comparisons are only valid within the same bleaching group.

Table 4
Mean (SD) of baseline shade scores and ΔVS.

Bleaching group	**Age group**	**Baseline**	**15-day recall**		**6-month recall**	
			ΔVS	**ΔES**	**ΔVS**	**ΔES**
CB	All participants	9.9(1.4)	5.4 (1.9)	1.5 (4.2)	4.7 (2.7)	3.3 (3.4)
	< 40 years old	9.6(1.0)	6.0 (1.2)	2.6 (4.0)	5.4 (2.2)	4.9 (2.7)
	≥ 40 years old	10.6 (2.0)	3.9 (2.5)	0.2 (4.3)	3.8 (3.3)	1.7 (3.3)
IOB	All participants	10.7 (1.9)	3.3 (2.8)	1.0 (3.4)	3.6 (2.4)	2.9 (3.1)
	< 40 years old	10.5 (2.0)	3.5 (2.7)	1.3 (3.6)	4.3 (2.4)	3.5 (3.0)
	≥ 40 years old	10.9 (1.7)	3.0 (2.9)	0.6 (3.3)	2.6 (2.1)	2.0 (3.2)
HB	All participants	10.6 (2.2)	4.0 (2.9)	5.6 (2.5)	4.6 (3.1)	5.1 (3.6)
	< 40 years old	10.2 (1.9)	4.4 (1.7)	6.1 (2.3)	5.8 (2.7)	6.2 (2.4)
	≥ 40 years old	11.0 (2.5)	3.5 (3.8)	4.3 (2.6)	3.4 (3.2)	3.0 (4.7)

bleaching treatment compared to both techniques when used individually (Kothari, Jum'ah et al. 2020). The current clinical trial aimed to investigate the impact of these three vital tooth bleaching protocols on OHRQoL. The OHIP-14 is a commonly used and reliable instrument for assessing OHRQoL outcomes, which has been validated among different age groups and in several countries, including New Zealand (Hongxing, List et al. 2014, Morgan, Jum'ah et al. 2015). The first null hypothesis was rejected because all bleaching protocols were associated with a significant reduction/improvement in overall OHIP-14 scores at the 15-day and 6-month recalls. This finding aligns with other studies despite using different bleaching protocols (McGrath, Wong et al. 2005, Meireles, Goettems et al. 2014). The results indicated that all investigated vital tooth bleaching protocols greatly improved an individual's self-perception of dentofacial aesthetics. All groups also experienced a significant improvement in the functional limitation domain. However, this effect was more pronounced in the CB and IOB groups compared to the HB group at the 15-day recall. There was no difference between the three groups at the 6-month recall, which may suggest that the positive impact of HB on appearance requires more time to be perceived by the individual and the surrounding community, which may be attributed to the slower whitening effect of such a protocol. One study reported that the positive impact of tooth bleaching on the functional limitation domain is not immediate and requires one month to be perceived (Bersezio, Estay et al. 2019). The most significant improvement was observed in the psychological discomfort domain for CB and IOB, reflecting the positive impact of tooth bleaching on psychological well-being that persisted for up to 6 months. This change reached statistical significance only in the CB and IOB groups, and a similar pattern was observed in the physical pain, psychological discomfort, physical disability, psychological disability, social disability, and handicap domains. The lack of significant improvement in these domains in the HB group can be attributed to the slower whitening effect of such a bleaching protocol and the inconvenience associated with using custom bleaching trays. Unlike the CB and HB groups, participants who received IOB did not exhibit any improvement in OIDP scores ($p = 0.863$), leading to the partial rejection of the second null hypothesis. The disparity in the findings between the two instruments can be attributed to differences in the scoring systems and the content of the two instruments. Some studies have reported moderate agreement between the two, while others have reported the superior performance of the OHIP-14 (Baker, Pankhurst et al. 2006). Furthermore, OHIP-14 seemed to have superior content validity due to its sensitivity to less severe impacts than OIDP (Soe, Gelbier et al. 2004, Hongxing, List et al. 2014). Vital bleaching treatments did not have a consistent positive impact on

Table 5
Spearman's correlation between shade improvement and QoL outcomes. P-value < 0.05 (in bold) is considered a significant correlation between the two variables.

		All participants		< 40 years		⩾ 40 years	
QoL Outcome	Recall	Spearman's correlation	p-value	Spearman's correlation	p-value	Spearman's correlation	p-value
OHIP overall	15 days	0.23	**0.025**	0.29	**0.023**	0.03	0.852
	6 months	0.03	0.757	−0.01	0.960	−0.04	0.820
Functional limitation	15 days	0.09	0.370	0.20	0.124	−0.14	0.430
	6 months	−0.10	0.366	−0.09	0.531	−0.14	0.418
Physical pain	15 days	0.20	0.055	0.15	0.246	0.07	0.667
	6 months	0.13	0.220	−0.03	0.838	0.13	0.438
Psychological discomfort	15 days	0.24	**0.017**	0.23	0.074	0.14	0.424
	6 months	0.08	0.477	−0.07	0.612	−0.01	0.947
Physical disability	15 days	0.01	0.915	0.09	0.493	−0.11	0.518
	6 months	0.12	0.270	0.08	0.569	0.15	0.395
Psychological disability	15 days	0.11	0.271	0.20	0.117	−0.13	0.449
	6 months	−0.17	0.112	−0.17	0.225	−0.26	0.126
Social disability	15 days	0.09	0.394	0.17	0.184	0.04	0.836
	6 months	−0.01	0.908	0.05	0.750	−0.02	0.918
Handicap	15 days	0.09	0.360	0.08	0.524	0.10	0.560
	6 months	0.02	0.861	0.13	0.382	−0.10	0.554
OIDP overall	15 days	−0.10	0.326	−0.04	0.758	−0.28	0.103
	6 months	0.00	0.974	−0.03	0.829	0.01	0.932

OHRQoL in older adults. The overall OHIP-14 scores significantly improved in all groups except the HB group ($p = 0.474$). Similar findings were reported by Bruhn et al. (Bruhn, Darby et al. 2012), who observed no improvement in overall OHIP-14 scores after applying 14% hydrogen peroxide whitening strips. The positive impact of CB treatment observed in this study on the majority of subscales was also less evident in the elderly group. The physical disability domain was the only subscale that exhibited a statistically significant group–time interaction ($p = 0.004$). Such findings can be related to the lower efficacy and effectiveness of the bleaching treatment in the elderly group (Kothari, Jum'ah et al. 2020). Furthermore, it has been reported that older subjects can be more resilient and habituated to their dental appearance (Hagglin, Berggren et al. 2005, Meireles, Goettems et al. 2014).

The number of dropouts/withdrawals was relatively high; the number of participants who followed up at 6 months was lower than originally intended (60% of those initially recruited). A larger sample size would have improved precision and revealed subtle yet clinically relevant differences among the studied bleaching protocols. The studied cohort primarily consisted of young participants (62%) and females (62%), which could potentially limit the trial's generalizability to other demographic groups, such as the elderly and males.

However, the findings of this study demonstrated that several factors, particularly age, can influence the impact of vital tooth bleaching on OHRQoL. Clinicians should consider this when caring for patients undergoing bleaching treatment to achieve the best improvement in aesthetics with minimal side effects and the most significant possible impact on OHRQoL. This study has several limitations, including the predominance of participants from the student and university staff population at the University of Otago, which may introduce a risk of selection bias. The sample predominantly comprised young participants, which limits generalizability to older adults. Five blinded and calibrated examiners were involved in the colour examination at different times. Despite the calibration, there is a potential risk of slight variations in shade determination by individual examiners. Additionally, the study's sample size is a limiting factor. The study was designed to detect a high effect size between participants from the study groups. An experimental design with larger sample sizes would be advantageous to rule out the possibility of small but clinically significant differences between groups. Therefore, future studies with larger sample sizes will be instrumental in addressing the impact of vital tooth bleaching on OHRQoL in specific age groups. Furthermore, because there was no correlation between tooth colour improvement as assessed by the clinician, it may be worthwhile to explore the development of tooth whiteness scales that patients can use to assess whether there is a correlation between tooth colour improvement and OHRQoL parameters.

5. Conclusion

The three vital tooth bleaching protocols demonstrated a positive impact on OHRQoL. However, this impact was most consistently observed across all domains and age groups in the CB group. The positive impact may be less pronounced in older age groups, which should be carefully considered when prescribing tooth bleaching treatments.

Ethical statement

Ethical approval was obtained from the University of Otago Human Ethics Committee (Application no. H18/019), and the study was conducted in full accordance with the World Medical Declaration of Helsinki.

CRediT authorship contribution statement

Ahmad Jum'ah: Conceptualization, Methodology, Writing – original draft, Visualization, Supervision. **Siddharth Kothari:** Conceptualization, Methodology, Validation, Formal analysis, Data curation, Writing – original draft, Writing – review & editing, Visualization, Supervision. **Andrew R. Gray:** Methodology, Validation, Formal analysis, Data curation, Supervision. **Jithendra Ratnayake:** Validation, Formal analysis, Writing – original draft, Writing – review & editing. **Felicity Leov:** Methodology. **Karl Lyons:** Conceptualization, Validation, Writing – review & editing, Supervision. **Paul A. Brunton:** Conceptualization, Methodology, Validation, Writing – review & editing, Supervision.

Declaration of Competing Interest

The authors declare that they have no known competing financial interests or personal relationships that could have appeared to influence the work reported in this paper.

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